

Cc: Loiseau, Patrick(WS)[Loiseaup@NorthAmerica.msx.merck.com]; Rao, Naveen A.[naveen_rao@merck.com]; Desmond, Ruth V.[desmond@NorthAmerica.msx.merck.com]
To: Kaufman, Keith D.[keith_kaufman@merck.com]
From: Pillai, Prita
Sent: Thur 8/17/2000 12:53:05 PM
Importance: Normal
Subject: RE: Abstract for EADV
Shapiro revised.doc

Is this any better?

Ruth asked me to forward the data to Jerry so that he could write a general abstract.

From: Kaufman, Keith D.
Sent: Thursday, August 17, 2000 10:29 AM
To: Pillai, Prita
Cc: Loiseau, Patrick (WS); Rao, Naveen A.; Desmond, Ruth V.
Subject: RE: Abstract for EADV

Still misleading, and the safety section is deceptive. The fact that we have lost most of the patients by Year 5 and that most of the patients with sexual AEs have dropped out of the study does not really permit you from making the statement that '99.4%' of patients at Year 5 had not sexual AEs.

How did Jerry write this? Where did he get the data from?

From: Pillai, Prita
Sent: Wednesday, August 16, 2000 6:36 PM
To: Kaufman, Keith D.
Cc: Loiseau, Patrick (WS); Rao, Naveen A.; Desmond, Ruth V.
Subject: RE: Abstract for EADV

Keith,

Jerry wrote the abstract. I put in your revisions as I interpreted them. Can you please see if this is any better.

Thank you

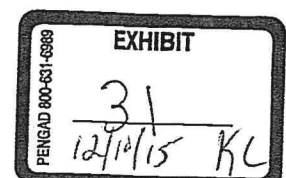
prita

<<File: Shapiro revised.doc>>

From: Kaufman, Keith D.
Sent: Wednesday, August 16, 2000 5:56 PM
To: Pillai, Prita
Cc: Loiseau, Patrick (WS); Rao, Naveen A.; Desmond, Ruth V.
Subject: RE: Abstract for EADV

Prita-

Well, not quite. Several errors, starting with the first sentence - 1553 men did *not* enroll in a 60 month study. The study was a 12 month study, with 4 extensions (1 per year). You are also using the 'no change' category for global photos as a positive for finasteride and a negative for placebo - definitely not appropriate. And how did we get 99.4% of patients on finasteride with no sexual adverse experiences?



Keith

From: Pillai, Prita
Sent: Wednesday, August 16, 2000 5:37 PM
To: Kaufman, Keith D.
Cc: Loiseau, Patrick (WS); Rao, Naveen A.; Desmond, Ruth V.
Subject: FW: Abstract for EADV

Hi Keith,
Attached is Jerry Shapiro's abstract for the EADV. Could you please review this and let me know if there are any errors in the content of the abstract. Please note that the grammatical errors will be corrected by our editing department.
Thank you

From: Kope, Susan
Sent: Wednesday, August 16, 2000 4:44 PM
To: Pillai, Prita
Subject: Abstract for EADV

<<File: GENEVA~1.DOC>>

J. SHAPIRO

Propecia: New Clinical Data – Five-Year Experience

One thousand five hundred fifty three men aged 18-41 with Norwood/Hamilton State II-V androgenetic alopecia ~~were enrolled~~ participated in a 60-month double-blind placebo-controlled study ~~not true – only the # patients who entered the last extension~~ (N~680) participated in a 60 month study. The study was a 12 month study, with 4 extensions (1 per year). Four hundred twenty seven patients had Month 60 hair count data, which showed statistically significant higher hair counts in the finasteride group compared to placebo but the 427 patients includes 4 treatment groups, not just finasteride and placebo continuous groups. This difference was maintained throughout the five year treatment period and ~~became~~ emerging greater over time. The difference in hair counts between the finasteride group and the placebo group within a 1-inch circular target area at Month 60 was 278 hairs. No patients in the finasteride group had any decrease in hair counts ~~not true – correct answer is 34%~~ while 100% of the placebo group had a decrease in hair counts as compared to baseline. Five hundred sixty patients had Month 60 global photography. The peak effect was seen at 24 months in the finasteride group. After 60 months, using global photography, 91% of the finasteride group showed either stabilization or improvement. Forty eight percent showed improvement. ~~During the 60 month period, 94% of the placebo group showed no improvement again, you can't use the no change category as a positive for finasteride ['stabilization'] and a negative for placebo . The placebo group worsened over the 60 months with 94% showing no improvement. The drug was well tolerated with and at year five, 99.4% this is totally misleading, as you have weeded out the dropouts with the sexual AEs (N=323) of the finasteride group experienced~~ ing no sexual adverse effects.

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